

§ 423.2004 Right to ALJ review of IRE notice of dismissal.

(a) An enrollee has a right to have an IRE's dismissal of a request for reconsideration reviewed by an ALJ if:

(1) The enrollee files a request for an ALJ review within 60 calendar days after receipt of the written notice of the IRE's dismissal.

(2) The enrollee meets the amount in controversy requirements of § 423.1970.

(3) For purposes of this section, the date of receipt of the IRE's dismissal is presumed to be 5 calendar days after the date of the written dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the entity specified in the IRE's dismissal.

(b) If the ALJ determines that the IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the IRE for a reconsideration.

(c) An ALJ's decision regarding an IRE's dismissal of a reconsideration request is binding and not subject to further review. The dismissal of a request for ALJ review of an IRE's dismissal of a reconsideration request is binding and not subject to further review, unless vacated by the MAC under § 423.2108(b).

§ 423.2008 Parties to an ALJ hearing.

(a) *Who may request a hearing.* Only an enrollee (or an enrollee's representative) may request a hearing before an ALJ.

(b) *Who are parties to the ALJ hearing.* The enrollee (or the enrollee's representative) who filed the request for hearing is the only party to the ALJ hearing.

§ 423.2010 When CMS, the IRE, or Part D plan sponsors may participate in an ALJ hearing.

(a) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any.

(b) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the hearing process.

(1) For non-expedited hearings, any request by CMS, the IRE, and/or the Part D plan sponsor to participate must be made within 5 calendar days of receipt of the notice of hearing.

(2) Within 5 calendar days of receipt of a request to participate in a non-expedited hearing, the ALJ must notify the entity, the Part D plan sponsor, if applicable and the enrollee of his or her decision on the request to participate.

(3) For expedited hearings, any request by CMS, the IRE, and/or the Part D plan sponsor to participate must be made within 1 calendar day of receipt of the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(4) Within 1 calendar day of receipt of a request to participate in an expedited hearing, the ALJ must notify the entity, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to participate.

(c) The ALJ has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate.

(d) Participation may include filing position papers or providing written testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee to the hearing.

(e) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing.

(f) CMS, the IRE, and/or the Part D plan sponsor must submit any position papers within the timeframe designated by the ALJ.

(g) The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

§ 423.2014 Request for an ALJ hearing.

(a) *Content of the request.* The request for an ALJ hearing must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following:

§ 423.2016

42 CFR Ch. IV (10–1–16 Edition)

(1) The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

(2) The name, address, and telephone number of the appointed representative, as defined at § 423.560, if any.

(3) The appeals case number assigned to the appeal by the IRE, if any.

(4) The prescription drug in dispute.

(5) The plan name.

(6) The reasons the enrollee disagrees with the IRE's reconsideration.

(7) A statement of any additional evidence to be submitted and the date it will be submitted.

(8) A statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(c) *When and where to file.* Consistent with §§ 423.1972(a) and (b), the request for an ALJ hearing after an IRE reconsideration must be submitted:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration.

(2) With the entity specified in the IRE's reconsideration.

(i) If the request for hearing is timely filed with an entity other than the entity specified in the IRE's reconsideration, the deadline specified in § 423.2016 for deciding the appeal begins on the date the entity specified in the IRE's reconsideration receives the request for hearing.

(ii) If the request for hearing is filed with an entity, other than the entity specified in the IRE's reconsideration, the ALJ hearing office must notify the appellant of the date of receipt of the request and the commencement of the adjudication timeframe.

(d) *Extension of time to request a hearing.* (1) Consistent with § 423.1972(b), if the request for hearing is not filed within 60 calendar days of receipt of

the written IRE's reconsideration, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must give the reasons why the request for a hearing was not filed within the stated time period, and must be filed with the entity specified in the notice of reconsideration.

(4) If the ALJ finds there is good cause for missing the deadline, the time period for filing the hearing request will be extended. To determine whether good cause for late filing exists, the ALJ uses the standards set forth in §§ 405.942(b)(2) and (b)(3) of this chapter.

(5) If a request for hearing is not timely filed, the adjudication period in § 423.2016 begins the date the ALJ grants the request to extend the filing deadline.

§ 423.2016 Timeframes for deciding an Appeal before an ALJ.

(a) *Hearings.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, the ALJ must issue a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(2) The adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the entity specified in the IRE's reconsideration, or, if it is not timely filed, the date that the ALJ grants any extension to the filing deadline.

(b) *Expedited hearings.* (1) Standard for expedited hearing. The ALJ must provide an expedited hearing decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or the ALJ determines that